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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/132,593	08/11/1998	ASGEIR SAEBO	21440/9015	9659

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/10/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/132,593

Applicant(s)

SAEBO ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 24.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The Request for a Continued Examination (RCE) under 37 CFR 1.114) based on parent Application No. 09/132593 filed on January 14, 2002 is acceptable and a RCE has been established. An action on the RCE follows.
2. The terminal disclaimer filed on August 2, 2001 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,015,833 has been reviewed and is accepted. The terminal disclaimer has been recorded. Note the terminal disclaimer filed on January 14, 2001 has not been entered because it is a duplicate of the terminal disclaimer filed August 2, 2001.

Claim Objection

3. Claim 8 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 8 has not been further treated on the merits.

Claim Rejections 35 U.S.C. 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims recite compounds “c9,t11-octadecanoic acid alkyl ester” and “t10,c12-octadecanoic acid alkyl ester,” however, the specification or the claims provide no description of

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these compounds. Note the expression "octadecanoic acid" is used in the art to denote C18 saturated fatty acid. Claim 4, the base claim, is drawn to composition containing unsaturated fatty acids, octadecadienoic acid. Expressions "c9,t11-octadecanoic acid alkyl ester" and "t10,c12-octadecanoic acid alkyl ester" have not been used in the art. One skilled in the art would not know how to make and/or use the compounds herein.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 5 recites the limitation "the ester" in line 1. There is insufficient antecedent basis for this limitation in the claim. Note the claim appears to be drawn to an ester composition. It is not clear what "the ester" refer to.

9. Claim 6 recites the limitation "the ester" in line 1. There is insufficient antecedent basis for this limitation in the claim. Note the claim appears to be drawn to an ester composition. It is not clear what "the ester" refer to.

10. Claim 5 recites the limitation "c9,t11-octadecanoic acid alkyl ester" in lines 2 and 4. There is insufficient antecedent basis for this limitation in the claim.

11. Claim 6 recites the limitation "t10,c12-octadecanoic acid alkyl ester" in lines 2 and 4. There is insufficient antecedent basis for this limitation in the claim.

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12. Claims 5 and 6 are also indefinite as to what c9,t11- or t10,t12 octadecanoic acid alkyl esters are. Note the specification has provided no description of these compounds and the examiner could not find any references regarding to these compounds.

Claim Rejections 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,554,646 of record) in view of applicants' disclosure at page 11, line 13-25 in the specification, Cain et al. (WO 97/18320, IDS April 13, 2000), Chin et al. (IDS, November 23, 1999) and Baltes et al. (US Patent 3,162,658, IDS May 23, 1999).

Cook'646 teach an active form conjugated linoleic acid, i.e., 10,12-octadecadienoic acid and 9,11-octadecadienoic acid, which including ester, salt and free acid of conjugated linoleic acid. See. Particularly, column 1 lines 65-67, column 2, line 1 and column 4, lines 1-9. The conjugated linoleic acid may be obtained through isomerization of safflower oil. See column 2, lines 12-45. Cook et al. further teach a food product comprising the said active form of conjugated linoleic acid. See, particularly, column 1, lines 39-60 and examples 1-4. The feeding may also comprising phosphatides. See, column 5, line 47. '646 also teach a safe and effective method for reducing body fat in animal by administering the said food product. See, particularly, the abstract. c9,t11- and t10,c12- isomer are predominantly major isomer of the conjugated linoleic acid active form of Cook'646. See, particularly, column 4, lines 50-55.

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Cook et al. do not teach expressly the conjugated linoleic acid active form further comprising the regio isomers 8,10- and an 11,13- octadecadienoic acid derivative, or specify the particular amounts of each 9, 11 and 10, 12 isomers of octadecadienoic acids, or the amount of phosphatides.

However, since the preferred amounts of the regio isomers 8,10- and an 11,13- octadecadienoic acid derivative in the claimed invention are limited to less than 2 percent, this amount includes zero percent of the regio isomers as disclosed by Cook. Thus, Cook' teachings meet this limitation. Chin et al. teach that it is known that c9,t11- conjugated linoleic acid isomer is an active form of conjugated linoleic acid. See, particularly, page 185, the abstract. Regarding the limitation of the particularly amount of phosphatidyl residue, note as disclosed at page 11, line 13-25 in the specification, it is known that safflower oil contain about 0.4-1.0 % of phosphatidyl residue. It would have been reasonably expected that isomerized Safflower oil (also is the starting material herein) containing phosphatidyl residue. Cain et al. further teaches a CLA composition made from sunflower oil contains 48.9 % of c9,t11, 51.1 % of t10, 12c linoleic acid or their esters. See, particularly, examples 6 at page 16, and example 18 at page 36, and claim 7. The composition is suitable for food products. See, particularly, claim 14.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a conjugated linoleic alkyl ester mixture from sunflower oil or safflower oil comprising c9,t11- and t10, c12-octadecadienoic moieties without/or with less than 2% of 8,10- and 11,13- octadecadienoic ester and employ the mixture in food products.

A person of ordinary skill in the art would have been motivated to make a conjugated linoleic alkyl ester mixture from sunflower oil or safflower oil comprising c9,t11- and t10, c12-octadecadienoic moieties without/or with less than 2% of 8,10- and 11,13- octadecadienoic ester and employ the mixture in food products because 8,10- and 11,13- octadecadienoic esters are known not to be required in the active form of conjugated linoleic acid and the c9,t11 and t10,c12 isomers are known to be the preferred isomers in food products. Further, alkyl ester of c9,t11- and t10, c12-octadecadienoic acids are known to be similarly useful as the free acid and the other esters.

3. Claim 7 would have been obvious for reasons discussed above, and in further view of Baltes et al. (US Patent 3,162,658, IDS May 23, 1999).

Claim 7 recites a particular process of making as a limitation of the claimed composition. Note the claim read on a composition of matter, not a method of making. It is well settled patent law that "Even though product-by-process claims are limited by and defined by process, determination of patentability is based on the product itself. The patentability of the product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by different process." *In re Thorpe*, 777F.2d 695,698, 227 USPQ 964, 966(Fed. Cir. 1985). It is applicants' burden to show an unobvious difference due to the particular process herein (See, MPEP 2113). Further, Baltes et al. teach that employment of low alkali alcoholate as catalysts for isomerization of unconjugated polyethenoid fatty acid compounds to conjugated isomers is known. See, column 2, lines 16-35, column 5, lines 5-21 and the claims. Therefore, it would have been obvious to one of ordinary skill in the art at the

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time the claimed invention was made, to obtain conjugated linoleic acid from safflower oil through the isomerization process taught by Baltes.

Response to The Arguments

Applicants' amendments and remarks, and the declaration of Asgeir Sæbo have been fully considered, but are not persuasive for reasons discussed below.

Applicants asserted that the composition of Cook et al. would inherently containing large amounts of t8,t10- and t11,t13- octadecadienoic isomers. In supporting the assertion, applicants cited Sugano and evidence showing t10,c12 isomer may be isomerized to c11, t13 isomer (declaration of Asgeir Sæbo). The assertion is not persuasive. First, the data presented by a applicant is not convincing because the data shows t10,c12 isomer may isomerized to c11, t13 isomer at 220 °C, much higher than the temperature employed by Cook (180 °C); Second, The procedure employed by Sugano is substantially different from the procedure employed by Cook et al. (see example 1, column 2 in Cook et al.). The particularly differences are a) Cook use Potassium salt and Sugano use Sodium salt; b) reaction time is different; c) the scale is different (1000 g of starting materials in Cook, 50 g in Sugano); d) ratio of starting materials/ethylene glycol (1:1 in Cook et al. and 1:6 in Sugano); e) starting materials are different (safflower oil in Cook et al. and >99% pure linoleic acid in Sugano). All these differences would have provided reasonable expectation that composition of Cook may be different from the composition of Sugano. Further, the arguments would be moot in view of Cain et al. Cain et al. teaches a composition comprising conjugated linoleic acid moieties. The conjugated linoleic acid moieties

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are composed of 48.9 % of c9,t11, 51.1 % of t10, 12c linoleic acid moieties. The analysis was carried out with gas chromatography and no other isomer of conjugated linoleic acid is detected. See, particularly, the example 18 at page 36.

Further, applicants have not provided any evidence showing the criticality, or unexpected benefit of CLA composition containing less than 2% of 8,10- and 11,13- octadecadienoic isomers as compared to CLA composition containing more than 2% of t8,t10- and t11,t13- octadecadienoic isomers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang
April 5, 2002